Remarks

Entry of the foregoing amended claims is respectfully requested. Applicant gratefully acknowledges the withdrawal of claim objections; and the rejections under 35 U.S.C. §101; and §112, second paragraph.

Applicant acknowledges the requirements for:

(a) Submission of a certified copy of the priority application, UK Patent Application No. 01153823.4;

(b) Sequence disclosures and amendments to the specification in accordance with 37 C.F.R. §1.821-1.825.

The required documents will be submitted in due course, and in any event will be submitted promptly upon an indication of the allowability of the foregoing amended claims.

Enablement

The Examiner has rejected claims 1-3, 10-12, 17, 18, and 21 under 35 U.S.C. §112, first paragraph, as not being enabled by the specification, on the grounds that the claims are broader than the specific point mutations disclosed in the specification.

In response, by the foregoing amendment, all claims have been amended to recite the particular mutants identified in the specification, which the Examiner indicated in the Final Office Action to be enabled by the specification (see p. 5, and page 15, concluding paragraph).

The Examiner has not explicitly entered a rejection of the claims on the grounds of enablement to assert that the claims are limited to an *in vivo* method and kit, however, in the interests of completeness, Applicant submits as follows: in the specification and the examples in this application, several tests described were

conducted in cell lines, a generally accepted model for determining *in vivo* activity. (See pp. 46-56). The particular mutants now being claimed have been shown to be active in living cells. Accordingly, the particular mutants demonstrated to be active in cell lines would be expected to be active *in vivo*. Since the currently amended claims now specify the particular mutants that the Examiner has recognized are enabled, the limitation to an *in vitro* is neither reasonable or necessary, and it is respectfully submitted that the currently amended claims are enabled as submitted herein

Anticipation and Obviousness

The Examiner has rejected claims 1, 2, 10, 11, 17 and 21 under 35 U.S.C. §102 as anticipated by Williams, *et al*, WO 00/14114. The Examiner has rejected claims 1-3, 10-12, 17, 18, and 21 under 35 U.S.C. §103 as obvious over Williams, *et al*, in view of Loregian, Marcello, Nashar[a] and , Nashar[b].

The Examiner has also indicated that amended claims similar to the above presented claims would be allowable. (Final Office Action , at 15). Applicant respectfully submits that the amended claims presented above are allowable in accordance with the Examiner's indication of allowability.

In particular, although Williams discloses mutant B-subunits of EtxB and CtxB, those were not covalently linked to a peptide, but were merely in admixtures (see Example 4 at p. 44). Applicants respectfully submit that in the present application, all of the claims require a peptide ***covalently linked*** to a toxin molecule. A covalent linkage of the peptide to the toxin molecule is not disclosed or suggested in Williams, *et al*, not would the claimed method and kit be obvious in view of the combination of Williams et al and the other cited art. There is no suggestion or recognition in the cited prior art of the benefit of the efficacy of using mutant B-subunits of EtxB and CtxB covalently linked to a peptide.

Accordingly, it is respectfully submitted that the claims of the present application are allowable over the prior art.

Respectfully submitted,

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